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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,920

05/05/2006

Hiroo Iwata

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7590

11/21/2008

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

11/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,920	<b>Applicant(s)</b> IWATA ET AL.	
	<b>Examiner</b> James S. Ketter	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,18,19,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 3-5,10-17,20,21 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/5/06, 11/21/06</u>  | 6) <input type="checkbox"/> Other: _____                          |



Art Unit: 1636

Applicant's election of the species of thiol as the monolayer in the reply filed on 24 July 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In view of the lack of prior art uncovered in the search for the elected species, all species are hereby **rejoined**, and the claims are examined in their entire scope as drafted.

Claims 3-5, 10-17, 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 25 and 26 are allowed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1636

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6-9, 18, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pei et al. (cited as reference AM on the IDS filed 21 November 2006).

Claim 1 is drawn to a method of introducing a nucleic acid into cells by electroporation, comprising the step (A) of loading a nucleic acid onto the surface of an electrode; the step (B) of adhering cells onto the surface of the obtained nucleic acid-loaded electrode; and the step (C) of applying electric pulses to the adhering adhered cells. Claim 2 is drawn to a method of introducing a nucleic acid into cells by electroporation, comprising the step (a) of providing an electrode with a cationic surface; the step (b) of adsorbing and loading a nucleic acid onto the cationic surface of an electrode; the step (c) of adhering cells onto the surface of the nucleic acid-loaded electrode obtained in the step (b); and the step (d) of applying electric pulses to the cells. Claim 6 specifies within claim 2 that step (b) is carried out by directly adsorbing nucleic acids on the cationic surface of an electrode only once, or adsorbing alternately nucleic acid and cationic polymer onto the surface in the order of the nucleic acid, cationic polymer and nucleic acid by an alternate adsorption method. Claim 7 specifies within claim 3 that the electrode is an electrode made of a metal selected from platinum, gold and aluminum. Claim 8 specifies within claim 3 that the electrode substrate is a gold electrode substrate. Claim 9 specifies within claim 8 that the gold electrode is a glass substrate or a transparent plastic substrate on which gold is deposited. Claim 18 specifies within claim 1 that the nucleic acid is DNA, RNA, antisense nucleic acid, siRNA or expression vector thereof. Claim 19 specifies within claim 1 that the nucleic acid is DNA or a part thereof which encodes a protein. Claim 22 specifies within claim 1 that step (C)

Art Unit: 1636

is carried out by providing a counter electrode facing to the nucleic acid-loaded electrode on which cells adhere and generating electric pulses between both electrodes. Claim 23 specifies within claim 2 that step (d) is carried out by providing a counter electrode facing to the nucleic acid-loaded electrode on which cells adhere and generating electric pulses between both electrodes.

Pei et al. teaches, e.g., at the Abstract, the assembly of alternating DNA and positively charged poly(dimethyldiallylammonium chloride) (PDDA) multilayer films by electrostatic layer-by-layer adsorption. At page 464, right-hand column, first and second full paragraphs, gold and quartz electrodes are both taught as substrates for the PDDA/DNA layers. However, this portion of Pei et al. does not specifically teach use of the resulting multilayer for electroporation of cells. At page 463, right-hand column, first full paragraph, however, it is suggested that “it is of crucial importance to control the adsorption and assembly of DNA to oppositely charged polymers, since cationic polymers have been tested for possible application as genetic support materials in gene transfection.” It would have been obvious to one of ordinary skill in the art to have employed the multilayer DNA/PDDA film of Pei et al. for electroporation, in view of the suggestion at page 463 of Pei et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK

2 December 2008

/James S. Ketter/

Primary Examiner, Art Unit 1636